

I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 3695

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. PROHIBITION OF AUTHORIZED GENERICS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

“(o) PROHIBITION OF AUTHORIZED GENERIC DRUGS.—

“(1) IN GENERAL.—Notwithstanding any other provision of this Act, no holder of a new drug application approved under subsection (c) shall manufacture, market, sell, or distribute an authorized generic drug, direct or indirectly, or authorize any other person to manufacture, market, sell, or distribute an authorized generic drug.

“(2) AUTHORIZED GENERIC DRUG.—For purposes of this subsection, the term ‘authorized generic drug’—

“(A) means any version of a listed drug (as such term is used in subsection (j)) that the holder of the new drug application approved under subsection (c) for that listed drug seeks to commence marketing, selling, or distributing, directly or indirectly, after receipt of a notice sent pursuant to subsection (j)(2)(B) with respect to that listed drug; and

“(B) does not include any drug to be marketed, sold, or distributed—

“(i) by an entity eligible for exclusivity with respect to such drug under subsection (j)(5)(B)(iv); or

“(ii) after expiration or forfeiture of any exclusivity with respect to such drug under such subsection (j)(5)(B)(iv).”.

Mr. LEAHY. Mr. President, recently I was pleased to introduce with Senators KOHL, GRASSLEY and SCHUMER, the Preserve Access to Affordable Generics Act of 2006, S. 3582. That bill was designed to improve the timely and effective introduction of generic pharmaceuticals into the marketplace.

It is no secret that prescription drug prices are rapidly increasing and are a source of considerable concern to many Americans, especially senior citizens and families. In a marketplace free of manipulation, generic drug prices can be as much as 80 percent lower than the comparable brand name version. Unfortunately, there are still some companies driven by greed that may be keeping low-cost, life-saving generic drugs off the marketplace, off pharmacy shelves, and out of the hands of consumers by carefully crafted anti-competitive agreements between drug manufacturers.

In 2001, and last Congress, I introduced a related bill, the Competition Act. That bill, which is now law, is small in terms of length but large in terms of impact. It ensured that law enforcement agencies could take quick and decisive action against companies seeking to cheat consumers by delaying availability of generic medicines. It gave the Federal Trade Commission and the Justice Department access to information about secret deals between drug companies that keep generic

drugs out of the market—a practice that not only hurts American families, particularly senior citizens, by denying them access to low-cost generic drugs, but also contributes to rising medical costs.

The Drug Competition Act, which was incorporated in the Medicare Modernization Act, was a bipartisan effort to protect consumers in need of patented medicines who were being forced to pay considerably higher costs because of collusive secret deals designed. It is regrettable that we must come to the floor again today and take additional action to prevent drug companies from continuing to find and exploit loopholes.

The bill I am introducing tonight with Senators ROCKEFELLER and SCHUMER is very important. It will provide incentives for generic companies to make the investments needed to introduce low-cost generic medicines for all our citizens.

The bill assures all Americans that the original intent of the Hatch-Waxman law is carried out. That law was to provide incentives for generic companies to challenge the validity of patents on medicines and provide incentives for generic companies to manufacture low-cost medicines. That incentive was simple.

Under Hatch-Waxman law, the first generic company, called the first-filer, which successfully develops a generic version of a patented drug and meets certain other requirements, can get a 180-day exclusivity period to be the only generic company to have permission to make and sell that generic drug.

That was called an exclusivity period because that is what the Congress intended—that generic company would have the exclusive right for 180 days to make the generic version of the patented medicine.

The problem is that recently brand-name companies have been labeling their own patented drugs also as a generic version of itself, or licensing others to make it, and selling both the brand-name version and the so-called generic version. This undercuts the potential profits of the “real” generic company and denies them what the Hatch-Waxman law promised and for a long time delivered—an exclusivity period lasting up to 180 days.

When the brand-name company offers a competing “fake” generic version of the drug, that can cut the profits of the real generic manufacturer greatly—thus making it less likely that a real generic company will even want to make the product.

The Rockefeller bill prevents the brand-name company from doing that for the 180-day exclusivity period. I hope my colleagues will join me in supporting this effort.

SUBMITTED RESOLUTIONS

SENATE CONCURRENT RESOLUTION 110—COMMEMORATING THE 60TH ANNIVERSARY OF THE HISTORIC 1946 SEASON OF MAJOR LEAGUE BASEBALL HALL OF FAME MEMBER BOB FELLER AND HIS RETURN FROM MILITARY SERVICE TO THE UNITED STATES

Mr. DEWINE submitted the following concurrent resolution; which was referred to the Committee on the Judiciary:

S. CON. RES. 110

Whereas Robert William Andrew Feller was born on November 3, 1918, near Van Meter, Iowa, and resides in Gates Mills, Ohio;

Whereas Bob Feller enlisted in the Navy 2 days after the attack on Pearl Harbor in 1941;

Whereas, at the time of his enlistment, Bob Feller was at the peak of his baseball career, as he had been signed to the Cleveland Indians at the age of 16, had struck out 15 batters in his first Major League Baseball start in August 1936, and established a Major League record by striking out 18 Detroit Tigers in a single, 9-inning game;

Whereas Bob Feller is the first pitcher in modern Major League Baseball history to win 20 or more games before the age of 21;

Whereas Bob Feller pitched the only opening day no-hitter in Major League Baseball history;

Whereas, on April 16, 1940, at Comiskey Park in Chicago, Bob Feller threw his first no-hitter and began the season for which he was awarded Major League Baseball Player of the Year;

Whereas Bob Feller served with valor in the Navy for nearly 4 years, missing almost 4 full baseball seasons;

Whereas Bob Feller was stationed mostly aboard the U.S.S. Alabama as a gunnery specialist, where he kept his pitching arm in shape by tossing a ball on the deck of that ship;

Whereas Bob Feller earned 8 battle stars and was discharged in late 1945, and was able to pitch 9 games at the end of that season, compiling a record of 5 wins and 3 losses;

Whereas 60 years ago, amid great speculation that, after nearly 4 seasons away from baseball, his best pitching days were behind him, Bob Feller had 1 of the most amazing seasons in baseball history;

Whereas, in the 1946 season, Bob Feller pitched 36 complete games in 42 starts;

Whereas, on April 30, 1946, in a game against the New York Yankees, Bob Feller pitched his second career no-hitter;

Whereas, in 1946, Bob Feller pitched in relief 6 times, saving 4 games;

Whereas, in 1946, Bob Feller routinely threw between 125 and 140 pitches a game, a feat not often seen today;

Whereas, in 1946, Bob Feller pitched 371½ innings and had 348 strikeouts;

Whereas, in 1946, Bob Feller had an earned run average of 2.18;

Whereas, in 1946, a fastball thrown by Bob Feller was clocked at 109 mph;

Whereas Bob Feller was the winning pitcher in the 1946 All Star Game, throwing 3 scoreless innings in a 12-0 victory by the American League;

Whereas, in 1946, Bob Feller led the American League in wins, shutouts, strikeouts, games pitched, and innings;

Whereas the baseball career of Bob Feller ended in 1956, but not before pitching his

third no-hitter against the Detroit Tigers on July 1, 1951, pitching 12 1-hit games, amassing 266 victories and 2,581 strikeouts, and leading the league in strikeouts 7 times;

Whereas Bob Feller was inducted into the Baseball Hall of Fame in 1962; and

Whereas Bob Feller, a beloved baseball figure known as "Bullet Bob" and "Rapid Robert," placed service to his country ahead of playing the game he loved and is a decorated war veteran: Now, therefore, be it

Resolved by the Senate (the House of Representatives concurring), That the Congress commemorates the 60th anniversary of the 1946 season of Bob Feller and his return from military service to the United States.

AMENDMENTS SUBMITTED AND PROPOSED

SA 4681. Mr. FEINGOLD (for himself, Mr. MCCAIN, Mr. CARPER, Mr. LIEBERMAN, Mr. JEFFORDS, Ms. COLLINS, and Ms. SNOWE) proposed an amendment to the bill S. 728, to provide for the consideration and development of water and related resources, to authorize the Secretary of the Army to construct various projects for improvements to rivers and harbors of the United States, and for other purposes.

SA 4682. Mr. INHOFE (for himself, Mr. BOND, Mr. COCHRAN, Mr. THUNE, Mr. DOMENICI, Mr. BURNS, Mr. CORNYN, and Mrs. HUTCHISON) proposed an amendment to the bill S. 728, *supra*.

SA 4683. Mr. INHOFE (for himself and Mr. BOND) submitted an amendment intended to be proposed by him to the bill S. 728, *supra*.

SA 4684. Mr. MCCAIN (for himself, Mr. FEINGOLD, and Mr. LIEBERMAN) proposed an amendment to the bill S. 728, *supra*.

TEXT OF AMENDMENTS

SA 4681. Mr. FEINGOLD (for himself, Mr. MCCAIN, Mr. CARPER, Mr. LIEBERMAN, Mr. JEFFORDS, Ms. COLLINS, and Ms. SNOWE) proposed an amendment to the bill S. 728, to provide for the consideration and development of water and related resources, to authorize the Secretary of the Army to construct various projects for improvements to rivers and harbors of the United States, and for other purposes; as follows:

Strike section 2007 and insert the following:

SEC. 2007. INDEPENDENT PEER REVIEW.

(a) DEFINITIONS.—In this section:

(1) CONSTRUCTION ACTIVITIES.—The term "construction activities" means development of detailed engineering and design specifications during the preconstruction engineering and design phase and the engineering and design phase of a water resources project carried out by the Corps of Engineers, and other activities carried out on a water resources project prior to completion of the construction and to turning the project over to the local cost-share partner.

(2) PROJECT STUDY.—The term "project study" means a feasibility report, reevaluation report, or environmental impact statement prepared by the Corps of Engineers.

(b) DIRECTOR OF INDEPENDENT REVIEW.—The Secretary shall appoint in the Office of the Secretary a Director of Independent Review. The Director shall be selected from among individuals who are distinguished experts in engineering, hydrology, biology, economics, or another discipline related to water resources management. The Secretary shall ensure, to the maximum extent prac-

ticable, that the Director does not have a financial, professional, or other conflict of interest with projects subject to review. The Director of Independent Review shall carry out the duties set forth in this section and such other duties as the Secretary deems appropriate.

(c) SOUND PROJECT PLANNING.—

(1) PROJECTS SUBJECT TO PLANNING REVIEW.—The Secretary shall ensure that each project study for a water resources project shall be reviewed by an independent panel of experts established under this subsection if—

(A) the project has an estimated total cost of more than \$40,000,000, including mitigation costs;

(B) the Governor of a State in which the water resources project is located in whole or in part, or the Governor of a State within the drainage basin in which a water resources project is located and that would be directly affected economically or environmentally as a result of the project, requests in writing to the Secretary the establishment of an independent panel of experts for the project;

(C) the head of a Federal agency with authority to review the project determines that the project is likely to have a significant adverse impact on public safety, or on environmental, fish and wildlife, historical, cultural, or other resources under the jurisdiction of the agency, and requests in writing to the Secretary the establishment of an independent panel of experts for the project; or

(D) the Secretary determines on his or her own initiative, or shall determine within 30 days of receipt of a written request for a controversy determination by any party, that the project is controversial because—

(i) there is a significant dispute regarding the size, nature, potential safety risks, or effects of the project; or

(ii) there is a significant dispute regarding the economic, or environmental costs or benefits of the project.

(2) PROJECT PLANNING REVIEW PANELS.—

(A) PROJECT PLANNING REVIEW PANEL MEMBERSHIP.—For each water resources project subject to review under this subsection, the Director of Independent Review shall establish a panel of independent experts that shall be composed of not less than 5 nor more than 9 independent experts (including at least 1 engineer, 1 hydrologist, 1 biologist, and 1 economist) who represent a range of areas of expertise. The Director of Independent Review shall apply the National Academy of Science's policy for selecting committee members to ensure that members have no conflict with the project being reviewed, and shall consult with the National Academy of Sciences in developing lists of individuals to serve on panels of experts under this subsection. An individual serving on a panel under this subsection shall be compensated at a rate of pay to be determined by the Secretary, and shall be allowed travel expenses.

(B) DUTIES OF PROJECT PLANNING REVIEW PANELS.—An independent panel of experts established under this subsection shall review the project study, receive from the public written and oral comments concerning the project study, and submit a written report to the Secretary that shall contain the panel's conclusions and recommendations regarding project study issues identified as significant by the panel, including issues such as—

(i) economic and environmental assumptions and projections;

(ii) project evaluation data;

(iii) economic or environmental analyses;

(iv) engineering analyses;

(v) formulation of alternative plans;

(vi) methods for integrating risk and uncertainty;

(vii) models used in evaluation of economic or environmental impacts of proposed projects; and

(viii) any related biological opinions.

(C) PROJECT PLANNING REVIEW RECORD.—

(i) IN GENERAL.—After receiving a report from an independent panel of experts established under this subsection, the Secretary shall take into consideration any recommendations contained in the report and shall immediately make the report available to the public on the Internet.

(ii) RECOMMENDATIONS.—The Secretary shall prepare a written explanation of any recommendations of the independent panel of experts established under this subsection not adopted by the Secretary. Recommendations and findings of the independent panel of experts rejected without good cause shown, as determined by judicial review, shall be given equal deference as the recommendations and findings of the Secretary during a judicial proceeding relating to the water resources project.

(iii) SUBMISSION TO CONGRESS AND PUBLIC AVAILABILITY.—The report of the independent panel of experts established under this subsection and the written explanation of the Secretary required by clause (ii) shall be included with the report of the Chief of Engineers to Congress, shall be published in the Federal Register, and shall be made available to the public on the Internet.

(D) DEADLINES FOR PROJECT PLANNING REVIEWS.—

(i) IN GENERAL.—Independent review of a project study shall be completed prior to the completion of any Chief of Engineers report for a specific water resources project.

(ii) DEADLINE FOR PROJECT PLANNING REVIEW PANEL STUDIES.—An independent panel of experts established under this subsection shall complete its review of the project study and submit to the Secretary a report not later than 180 days after the date of establishment of the panel, or not later than 90 days after the close of the public comment period on a draft project study that includes a preferred alternative, whichever is later. The Secretary may extend these deadlines for good cause.

(iii) FAILURE TO COMPLETE REVIEW AND REPORT.—If an independent panel of experts established under this subsection does not submit to the Secretary a report by the deadline established by clause (ii), the Chief of Engineers may continue project planning without delay.

(iv) DURATION OF PANELS.—An independent panel of experts established under this subsection shall terminate on the date of submission of the report by the panel.

(E) EFFECT ON EXISTING GUIDANCE.—The project planning review required by this subsection shall be deemed to satisfy any external review required by Engineering Circular 1105-2-408 (31 May 2005) on Peer Review of Decision Documents.

(d) SAFETY ASSURANCE.—

(1) PROJECTS SUBJECT TO SAFETY ASSURANCE REVIEW.—The Secretary shall ensure that the construction activities for any flood damage reduction project shall be reviewed by an independent panel of experts established under this subsection if the Director of Independent Review determines that—

(A) project performance is critical to the public health and safety;

(B) reliability of project performance under emergency conditions is critical;

(C) the project utilizes innovative materials or techniques; or

(D) the project design is lacking in redundancy, or the project has a unique construction sequencing or a short or overlapping design construction schedule.

(2) SAFETY ASSURANCE REVIEW PANELS.—At the appropriate point in the development of